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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,055	09/05/2003	Debbie Yaver	10322.200-US	8946

25907 7590 07/15/2005

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,055	YAVER ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11,27,34,36,42-44,46,50-56,69,70,75 and 79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,11,27,34,36,42-44,46,50-56,69-70, 75 and 79* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendment

1. The preliminary amendment filed September 5,2003 has been entered. Claims 2-10, 12-26,28-33,35, 37-42, 45, 47-49, 57-68, 71-74 and 76-78 have been cancelled. It is noted, that the amendment has two claim 53's. However the second claim 53, which appears on page 4 of the amendment, seems to have been misnumbered and is actually claim 55. Therefore, this claim is being treated as claim 55. Accordingly, claims 1,11, 27, 34, 36, 42-44, 46, 50-56, 69-70, 75 and 79 are under consideration.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 11, 27, 34, 36 and 42-43 are drawn to a method for determining the mode of action of an antimicrobial compound wherein a single sequence is selected from the plurality of sequences is obtained from *Bacillus subtillis*, classified in class 435, subclass 7.32.

II. Claims 1, 11, 34, 36 and 42-44 are drawn to a method for determining the mode of action of an antimicrobial compound wherein a single sequence is selected from the plurality of sequences is selected from the group of genes disclosed in Tables 4-21 classified in class 435, subclass 6.

III. Claims 1, 11, 34, 36, 42-43 and 46 are drawn to a method for determining the mode of action of an antimicrobial compound wherein the sequence is drawn to yerQ or a fragment thereof, classified in class 435, subclass 6.

IV. Claims 1, 11, 34, 36, 42-43 and 50-51 are drawn to a method for determining the mode of action of an antimicrobial compound comprising the SA0681 sequence or a fragment thereof which is obtained from *Staphylococcus aureus,* classified in class 435, subclass 7.33.

V. Claims 1, 11, 34, 36, 42-43, 50 and 52, drawn to a method for determining the mode of action of an antimicrobial compound comprising the SP1714 sequence or a fragment thereof which is obtained from *Staphylococcus aureus,* classified in class 435, subclass 7.33.

VI. Claims 1, 11, 34, 36, 42-43 and 53-54 are drawn to a method for determining the mode of action of an antimicrobial compound comprising the SP1045 sequence or a fragment thereof which is obtained from *Streptococcus pneumoniae*, classified in class 435, subclass 7.34.

VII. Claim 55 is drawn to a single isolated nucleic acid selected from the genes of Tables 4-23, classified in class 530, subclass 388.4.

VIII. Claim 56 is drawn to single substrate selected from the genes of Tables 4-21, classified in class 536, subclass 23.1.

IX. Claims 69-70 are drawn to a method for evaluating a compound for antimicrobial activity, classified in class 435, subclass 4.

X. Claim 75 is drawn to a method for screening for antimicrobial compounds, classified in class 435, subclass 32.

XI. Claim 79 is drawn to a set of at least two bacterial strains, classified in class 435, subclass 252.3.

3. The inventions are distinct, each from the other because of the following reasons:

(i) Inventions I, II, III, IV, V, VI, IX and X are related as distinct methods because they are different methods with different method steps; reagents; functions and each result in different final outcomes. First, the instant specification does not disclose that these methods would be used together, rather the specification beginning at page 2 states that the methods are separate and distinct. The methods are all unrelated as they comprise distinct steps and utilize different products which demonstrate that each method has a different mode of operation. Each invention performs its function using a structurally and functionally divergent material. For instance, the use of a single sequence is selected from the plurality of sequences is obtained from *Bacillus subtillis* in a method for determining the mode of action of an antimicrobial compound, is not necessary to practice the other methods. In this case, group IV is separate and distinct, from groups II, III, V, VI, IX and X, since only group IV comprises the SA0681 sequence or a fragment thereof which is obtained from *Staphylococcus aureus*. Therefore, each method is divergent with respect to the amounts of reagents used and their associated steps. For these reasons the inventions I, II, III, IV, V, VI, IX and X are patentably distinct.

Furthermore, searching the inventions of groups I, II, III, IV, V, VI, IX and X would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A method for screening for antimicrobial compounds requires a different search, than the other methods. Thus, a search drawn

to a method for screening for antimicrobial compounds is not necessary for a determination of novelty and unobviousness of the method of group II which comprises a method for determining the mode of action of an antimicrobial compound wherein a single sequence is selected from the plurality of sequences is selected from the group of genes of Tables 4-21. Furthermore, the method of group VI may be known even if the method of group IV is novel. In addition, the technical literature search for the method of group I and the method of groups I-VI and IX-X are not coextensive, since, for instance, the method group I may be characterized in the technical literature prior to discovery of the kit of group IV.

(ii) Inventions VII, VIII and XI are patentably different products. The inventions are distinct, each from the other because of the following reasons: Although there are no provisions under the section for "Related Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different products; restriction is deemed to be proper because these products appear to constitute patentably distinct inventions. Group VII is drawn to a nucleic acid, Group VIII is drawn to a substrate, and Group XI is drawn to a set of bacterial strains. The group directed to the nucleic acid is distinct physically, structurally and functionally, and are therefore patentably distinct, each group from the other. For instance, the bacterial strains of Group XI is unlike the substrate of Group VIII. The nucleic acid group VII is capable of encoding amino acids, unlike the substrate and bacterial strains of groups VIII and IX. Therefore, one group is not required to

practice the other. Each group comprises separate and distinct products that are not disclosed as being essential to the utility of the invention.

Furthermore, searching the inventions of groups VII, VIII and XI would impose a serious search burden. The inventions have a separate status in the art as shown by their distinct structure. Thus different proteins require different searches. A nucleic acid sequence search is not necessary for a determination of novelty and unobviousness of another unrelated bacterial strain. Moreover, a search of group VIII is not required to identify the bacterial strains of group XI. Furthermore, the bacterial strains of group XI may be known even if the substrate of group VIII is novel. In addition, the technical literature search for the bacterial strains of group XI and the nucleic acid of group VII are not coextensive, e.g., the nucleic acid of group VII may be characterized in the technical literature prior to discovery of the bacterial strains of group XI.

(iii) Inventions I-VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of group VII can be practiced with a materially different process such as with a method of encoding a particular amino acid. Moreover, the method of group I only identifies the nucleic acid of group VII, it does not require the use of the nucleic acid to practice the method. Therefore, the inventions have been shown as distinct.

Searching the inventions of groups I-VI and VII together would impose serious search burden. The inventions of groups I-VI and VII have acquired a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the nucleic acids and the method for determining the mode of action of an antimicrobial compound are not coextensive. Group VII encompasses nucleic acid sequences, and therefore not required for the search of groups I-VI. In contrast, the search for groups I-VI would require a text search for a method for determining the mode of action of an antimicrobial compound and would not necessarily encompass a search for the nucleic acid sequence of group VII. Moreover, even if the nucleic acid product were known, the method for determining the mode of action of an antimicrobial compound may be novel and unobvious in view of the preamble or active steps.

(iv) Inventions I, II, III, IV, V, VI, VIII, IX, X and XI are unrelated because these methods and products are not used or otherwise involved in any of the above recited methods.

4. The inventions of Groups I-XI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search any combination of the inventions of Groups I-XI together.

5. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group

requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order

to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Therefore applicant is reminded that is groups I, II, VII or VIII are selected, applicants must identify a single gene or nucleic acid which is to be searched in order for their election to be fully responsive.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
July 4, 2005